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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/871,125	05/31/2001	Michael W. Pariza	960296.97958	2562

7590

06/17/2003

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EXAMINER

HUI, SAN MING R

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 06/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/871,125

Applicant(s)

PARIZA ET AL.

Examiner

San-ming Hui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 9,15-17 and 19-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,10-14 and 18 is/are rejected.
- 7) ☒ Claim(s) 5-8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 24, 2003 has been entered.

The outstanding rejection under 35 USC 103 is withdrawn in view of the remarks and the teachings of Gowri et al. (from the IDS received March 24, 2003). The reasonable expectation of success of employing NDGA in controlling body fat is not provided in the cited prior art.

The method of controlling body fat in an animal employing NDGA is found to be free of prior art. Therefore, the search is extended to the specie, indomethacin. The claims will be examined to the extent it reads on the elected specie and invention.

Claims 1-47 are pending. As stated in the previous office action mailed November 19, 2002, claims 15-16 and 20-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention. Furthermore, claims 9, 17, and 19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected species.

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Claims 1-8,10-14, and 18 are examined on the merits herein to the extent they read on the elected invention and species.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 10-14, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verrando et al. (Biochemica et Biophysica Acta, 1981; 663: 255-265) and Miller et al. (Biochemical and Biophysical Research Communications, 1994; 198: 1107-1112) in view of Steinhart (Journal of Chemical Education, 1996;73(12):A302).

Verrando et al. teaches indomethacin can enhance the maturity of adipose tissue and fat accumulation in mouse ob 17 preadipocytes (See abstract, and page 263, last paragraph to page 264, first paragraph).

Miller et al. teaches CLA can prevent the endotoxin induced body fat and lean mass loss when employed as 0.5% in the rat diet (See page 1110, last paragraph; also page 1108, lower part of the page on Rat and chick experimental protocol).

The references do not teach to employ both CLA and indomethacin together to prevent weight loss in endotoxin affected animals. The references do not teach to employ the specific CLA, *trans*-10,*cis*-12-conjugated linoleic acid, in the method of Miller et al.

Steinhart teaches that CLA is a group of positional and geometric isomers of linoleic acid having a conjugated double-bond system starting at carbon 9, 10, or 11, wherein *trans*-10,*cis*-12-conjugated linoleic acid is one of the CLA (See Second paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ both CLA and indomethacin together to prevent weight loss in endotoxin affected animals. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the specific CLA, *trans*-10,*cis*-12-conjugated linoleic acid, in the method of Miller et al.

One of ordinary skill in the art would have been motivated to employ both CLA and indomethacin together to prevent weight loss in endotoxin affected animals because indomethacin is known to enhance the fat accumulation, i.e., prevent fat loss, and CLA is known to prevent body fat loss. Therefore, combining these two agents together in a method useful for the same purpose would be obvious (See *In re Kerkhoven* 205 USPQ 1069). One of ordinary skill in the art would have been motivated

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to employ the specific CLA, *trans*-10,*cis*-12-conjugated linoleic acid, in the method of Miller et al. because any CLA, including *trans*-10,*cis*-12-conjugated linoleic acid, would be reasonably expected to be similarly useful in prevent body fat loss in endotoxin affected animals.

Response to Arguments

Applicant's arguments with respect to claims 1-4, 10-14, and 18 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

Claims 5-8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned

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are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



San-ming Hui
Patent Examiner
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June 9, 2003